



September 5, 2018

Kierr International, LLC
% Raymond Blanche
Consultant
NST Consultants, Inc
641 Shunpike Road, Suite 311
Chatham, New Jersey 07928

Re: K181878

Trade/Device Name: Kierr Family of Devices, Model 272 Premier & Model 148 Pro Laser Hair
Growth Caps

Regulation Number: 21 CFR 890.5500

Regulation Name: Infrared Lamp

Regulatory Class: Class II

Product Code: OAP

Dated: May 9, 2018

Received: July 13, 2018

Dear Raymond Blanche:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at <https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm> identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see <https://www.fda.gov/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm>); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm>.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (<https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/>) and CDRH Learn (<http://www.fda.gov/Training/CDRHLearn>). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (<http://www.fda.gov/DICE>) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

**Jennifer R.
Stevenson -S3**

For Binita S. Ashar, M.D., M.B.A., F.A.C.S.
Director
Division of Surgical Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known)

K181878

Device Name

Kierr Family of Devices, 272 and 148 Laser

Indications for Use (Describe)

The Kierr Family of Devices, the 272 and 148 Laser Devices are indicated to promote hair growth in females with androgenetic alopecia who have Ludwig-Savin Classifications I - II, in males with androgenetic alopecia who have Norwood-Hamilton Classifications of IIa - V and for both, Fitzpatrick Classifications of Skin Phototypes I - IV.

Type of Use (Select one or both, as applicable)

Prescription Use (Part 21 CFR 801 Subpart D)

Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRASStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) Summary

August 15, 2018 Revised

Kierr International, LLC

Submitter's Contact Information

Name: Raymond R. Blanche
Address NST Consultants, Inc.
641 Shunpike Road, Suite 311
Chatham, NJ 07928
Telephone: (973) 539-7444
Facsimile: (973) 539-7445

Name of Device and Name/Address of Sponsor

Trade Name: Kierr Family of Devices, the 272 and 148 Laser
Sponsor Contact Information: Michael Anderson
Kierr International, LLC
863 East Downington Avenue
Salt Lake City, Utah 84105-3211
Telephone: 435-840-8199

Common or Usual Name: Lamp, non-heating, for promotion of hair growth
Classification Name: Infrared lamp per 21 CFR 890.5500
Classification Code: OAP (Laser, comb, hair)

Predicate Devices:

| Device Trade Name | Manufacturer |
|--------------------------|-----------------------------------|
| Diode Laser Cap K173678 | Cosmo Far East Technology Limited |

Reference Devices:

None

Date Prepared: May 9, 2018

Intended Use / Indications for Use

The Kiierr Family of Devices, the 272 and 148 Lasers are indicated to promote hair growth in females who have Ludwig-Savin Classifications of I – II males with androgenetic alopecia who have Norwood-Hamilton Classifications of IIa – V, and for both, Fitzpatrick Skin Phototypes I to IV.

Technological Characteristics

The Kiierr Family of Devices, the 272 and 148 Lasers each contain the listed number of diodes lasers configured within an outer cap helmet and protective inner liner. The use of diode lasers provides for a full coverage of the upper 1/3 of the head i.e., the area commonly covered with stylized hair. The Kiierr Family of Devices, the 272 and 148 Lasers are powered by a lithium-ion battery pack that contains an embedded controller chip. In all other area of design, manufacturing, and aesthetic appearance, the devices are identical.

Performance Data:

No clinical performance data was produced for this submission because the Kiierr Family of Devices, the 272 and 148 Lasers are the same devices as the predicate, the Diode Laser, cleared under K173678. All proposed devices and predicate devices are IDENTICAL and the same devices offered for PRIVATE LABEL by the manufacturer. They are the same device in optical, electronic, mechanical function and aesthetic appearance, as well as the same recommended clinical treatment regime. It is essential to understand that this class of device is manufactured by many different manufacturers, all using the same parts supplied by the same OEM suppliers. Hence, there are virtually no differences between the devices.

Substantial Equivalence

Both the Kiierr Family of Devices, the 272 and 148 Lasers and the Diode laser 272 use red light diode lasers, classified as class IIIa/3R laser systems by the IEC standard for allowable emission levels, which is a recognized standard by the FDA as well, and the adverse event profile is the same. The sponsor believes that there is no difference in the physical appearance or in the method of delivering the radiant energy of the systems and therefore, there are no variations in the therapeutic value or safety profile.

For these reasons, the Kiierr Family of Devices, the 272 and 148 Lasers overwhelmingly satisfies the FDA’s substantial equivalence with respect to intended use, technological and design characteristics.

The Kiierr Family of Devices, the 272 and 148 Lasers are prospective devices that will be manufactured by the ISO 13485 compliant contract manufacturer, on the same platform as the Diode Laser, predicate devices. There are no safety concerns raised by this process of manufacturing because the model 272 and 148 are the same devices the predicate manufacturer sells under its proprietary label and name.

Treatment Protocol

The Kiierr Family of Devices, the 272 and 148 Lasers and the identified predicates, possess the same treatment regime of 30 minutes, every other day, on non-consecutive days, for the initial treatment regime of 16 weeks.

The following Comparison Chart in support of substantial equivalence is provided:

| The Kiierr Family of Devices, the 272 and 148 Lasers | | Diode Laser 272 | Diode Laser 148 |
|--|---------------|-----------------|-----------------|
| LLLT Device Type | Laser diode | Laser Diode | Laser Diode |
| Use Application | OTC | OTC | OTC |
| Intended Use - Androgenetic Alopecia | Yes | Yes | Yes |
| Contain Laser Diodes-Class 3R, | Yes 272 & 148 | Yes 272 | Yes 148 |
| Optical Output – 5mW or less | Yes | Yes | Yes |
| Helmet Design | Yes | Yes | Yes |
| 650+/-5 nm. | Yes | Yes | Yes |
| Marketing Clearance –Females & Males, OTC | Yes | Yes | Yes |
| Passive Use-Hands Free | Yes | Yes | Yes |
| OAP Classification | Yes | Yes | Yes |
| Classification Name -Infrared Lamp | Yes | Yes | Yes |
| Common Usage Name - Lamp, Non-Heating | Yes | Yes | Yes |
| General & Plastic Surgery Committee | Yes | Yes | Yes |
| Skin Phototypes - I- IV | Yes | Yes | Yes |
| Hamilton-Norwood Iia-V Hair Loss Classification | Yes | Yes | Yes |
| Ludwig-Savin I – II Hair Loss Classification | Yes | Yes | Yes |
| Treatment- 16 weeks, for 30 minute treatment times three times a week on alternate days. | Yes | Yes | Yes |
| Device Class II | Yes | Yes | Yes |

The data presented in the Comparison Chart, demonstrates that all Kiierr models 272 and 148 devices are identical and equivalent, PRIVATE LABEL devices from the same manufacturer. The Models 272 and 148 will be manufactured on the same platform by the same manufacturer as the 272 and 148 Diode Lasers, by Cosmo Far East Technology, Ltd.

Based on this comparison and determination, the sponsor requests the FDA to clear the device via the 510(k) notice.

Over – The – Counter Testing Program

To test volunteer subjects for the suitability of the The Kiierr Family of Devices, the 272 and 148 Lasers 40 subjects were asked twenty-six questions, after being provided a standard retail package and a full owner's manual. The test subjects were given as long as they required to read and understand the product packaging and manual. No assistance was provided to them and they were not permitted to ask any questions of the interviewer. The interviewer then conducted the interview and filled in the responses from the subjects. The subjects were required to answer all questions correctly to be counted as PASS for the correct Self Selection or, to have made the correct decision to purchase the product or not; to assemble and use the product correctly and comprehend the hazards and maintenance procedures for the device. These decisions would be based upon their understanding of the Intended Use of the product and the manual.

If the questions were answered correctly, they were given a P for PASS. If any questions were answered incorrectly, they were given an F for FAIL. The number of subjects required to answer all questions correctly is 32 out of 40, for an 80% success rate.

The results of the Over-the-Counter testing demonstrate that the The Kiierr Family of Devices, the 272 and 148 Lasers comply with the requirements the FDA determined to be applicable. The test revealed an overall **90% pass rate** for the subject group of 40 male and female participants. The testing further demonstrates that age, education, socioeconomic group, race or medical hair loss status are not variants that prevent proper self-selection, usability and comprehension of hazards and maintenance procedures for the average consumer to successfully navigate the purchasing and use process of the The Kiierr Family of Devices, the 272 and 148 Lasers.

Based on this data, the sponsor believes that the The Kiierr Family of Devices, the 272 and 148 Lasers, for female and male users have met the requirements for OTC sale.

Electrical Safety and Electromagnetic Compatibility Testing Performance

The The Kiierr Family of Devices, the 272 and 148 Lasers were evaluated for conformance to recognized international standards. The following is a list of these evaluations and tests that were found to be in conformance:

1. IEC 60825-1 Edition 2.0 2007-03 Safety of Laser Products – Part 1: Equipment Classification and Requirements.
2. IEC 60601-1-2 Edition 3.0 2007-03 Medical Electrical Equipment – Part 1-2 General Requirements for Basic Safety and Essential Performance - Collateral Standard: Electromagnetic Compatibility – Part 1: Requirements and Tests.

Conclusion

Based on the technical comparisons between the The Kiierr Family of Devices, the 272 and 148 Lasers and the identified predicates it can be concluded that the Kiierr models are identical to the predicate devices in technical specifications. Since the Kiierr models are built using the identical platform with no difference between models, it can be concluded that all of the Kiierr models are equally safe. Therefore, it can be determined that the The Kiierr Family of Devices, the 272 and 148 Lasers are Substantially Equivalent to the identified predicates.